

PBO ($p=0.3854$). Adverse events (AEs) occurred in 77.3% and 59.9% of PGB- and PBO-treated pts, respectively; the most frequent with PGB were dizziness (28.2%) and somnolence (19.9%). 4 serious AEs were reported, 3 (1.7%) with PGB and 1 (0.6%) with PBO; none were considered related to treatment. 6.1% of PGB-treated pts discontinued due to AEs vs. 3.4% receiving PBO.

Conclusions: In pts with FM taking an SSRI or SNRI for comorbid depression, PGB significantly improved FM pain vs. PBO. The safety profile of PGB in these pts was consistent with previous studies and current product labelling.

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THU0322 FIBROMYALGIA ASCERTAINMENT IN YOUNG ADULTS FROM THE GENERAL POPULATION: WHAT CHANGES WITH THE 2010 ACR CRITERIA?

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Background: Since 2010, fibromyalgia is modelled as a syndrome of progressive severity where non-specific symptoms other than pain precede the establishment of clinical disease. Detecting those symptoms is expected to improve sensitivity by widening the spectrum of clinical features, namely in early stages of the disease. However, little is known about the frequency and predictors of the non-pain component of the fibromyalgia syndrome in early adulthood.

Objectives: To quantify the prevalence of fibromyalgia (2010 ACR), to describe its components – symptom severity score and widespread pain index – and to identify psychosocial predictors of the severity of symptom severity score and widespread pain using a population-based sample of male and female young adults.

Methods: Participants were part of the 21-year-old follow-up of the EPITeen cohort study, which was set up during the 2003/2004 school year and gathered subjects born in 1990 attending schools in Porto, Portugal ($n=1561$, 51.3% women). Data on socioeconomic (work situation, parental and individual education and household income), lifestyle factors (smoking, alcohol drinking and sports practice) and psychological characteristics (health-related quality of life, sleep quality, depressive symptoms, eating disorders and maladaptive personality traits) were collected using structured face-to-face and self-administered questionnaires. Data on fibromyalgia and the severity of its two main components were collected using the Fibromyalgia Survey Questionnaire. Medians of symptom severity score and widespread pain index severity were compared according to each psychosocial factor using the Mann-Whitney test or the Kruskal-Wallis one-way analyses of variance.

Results: The overall point-prevalence of fibromyalgia was 1.1%, higher in women than in men (1.5% vs. 0.7%, $p=0.110$). Women scored significantly higher both in symptom severity score (median (P_{25} ; P_{75})=3.0 (2.0; 5.0) vs. 2.0 (1.0; 4.0), $p<0.001$) and widespread pain index (median (P_{25} ; P_{75})=1.0 (0.0; 1.0) vs. 0.0 (0.0; 1.0), $p<0.001$). Both in female and male young adults, socioeconomic, lifestyle factors and psychological features were not significantly associated with higher scores in widespread pain index. Socioeconomic indicators, such as work situation (employed vs never worked: median (P_{25} ; P_{75})=4.0 (2.0; 5.0) vs 3.0 (2.0; 5.0), $p<0.01$), and lifestyle factors, such as smoking (smokers vs non-smokers: median (P_{25} ; P_{75})=4.0 (2.0; 5.0) vs 3.0 (2.0; 5.0), $p<0.05$), were significantly associated to higher scores in symptom severity score in female sex. Additionally, most adverse psychological characteristics (poor quality of life, decreased sleep quality, relevant depressive symptoms, eating disorders and maladaptive personality traits such as interpersonal distrust, interoceptive awareness and ineffectiveness) were significantly associated with higher scores in symptom severity score in both sexes.

Conclusions: In young adults, prevalence of fibromyalgia was similar to other high burden chronic diseases. Using the symptom severity score may be useful in widening case ascertainment to young adults whose main clinical manifestations are related to psychological distress.

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THU0323 BASAL fMRI DIFFERENCES BETWEEN MILNACIPRAN RESPONDERS AND NON-RESPONDER IN FIBROMYALGIA

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Background: There were comparison studies of regional cerebral blood flow between the responder group and the poor responder group to gabapentin and pregabalin in fibromyalgia (FM). Other brain imaging studies, such as positron emission tomography and fMRI, were needed to clarify the pathophysiology of FM and the characteristics of responders to gabapentin or pregabalin treatment.

Objectives: We studied basal fMRI differences between milnacipran responders and non-responder in patients with FM.

Methods: This research included 20 FM patients and 11 normal persons. We selected only females who were age and education level-matched in both groups to avoid bias. Tests were divided into clinical evaluation and fMRI imaging. Clinical evaluation was accomplished by principal investigator (rheumatology doctor) and included Korean fibromyalgia impact questionnaire (KFIQ), brief fatigue inventory (BFI), disease duration, widespread pain index (WPI), state anxiety inventory (SAI), and trait anxiety inventory (TAI). Changes in cerebral activation area were measured using BOLD contrast fMRI after application of both medium and high pressure stimuli to the left thumb nail bed.

Results: After treatment with milnacipran, 10 patients were considered 'responders', with decrease in pain of greater than 50% as evaluated by visual analogue scale. The remaining 10 patients were considered 'poor responders'. The results showed that there were more increased activities in left insula and right inferior frontal gyrus of responder group in response to high pressure stimuli ($p<0.05$) and in anterior cingulate and left cingulate gyrus of non-responder group in response to high pressure stimuli ($p<0.005$).

Conclusions: These regions can be susceptible to pain perception in these milnacipran treated FM patients.

Disclosure of Interest: None declared

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THU0324 IS BALANCE TRAINING EXERCISE PROGRAM EFFECTIVE IN FIBROMYALGIA SYNDROME?

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Background: Central nervous system dysfunction in fibromyalgia syndrome (FMS) may affect other sensorimotor functions of the patients, besides widespread pain. Balance disorder in FMS was stated in a few studies.

Objectives: To determine the effectiveness of the balance training exercise program in FMS and to find out the factors that associate with balance disorders in FMS.

Methods: A total of 68 patients, aged 18-65, diagnosed with FMS, joined in 6 weeks exercise program. The patients were randomly assigned into two groups. Group 1 ($n=35$) received flexibility exercises (15 min./day), balance exercises recommended by American Sport College (20 min./day) for 5 days a week and static (5min./day) and dynamic (5min./day) balance training with Kinesthetic Ability Trainer (KAT) 4000 device for 3 days a week (each one 5 min./day). Group 2 ($n=33$) received only flexibility program for 5 days a week. Patients were evaluated by means of balance, fall risk, functional level, quality of life and depression. Functional balance was measured by Berg Balance Scale (BBS), dynamic and static balance were assessed by Sport Kinesthetic Ability Trainer (KAT) 4000 device. Fall risk of the patients was specified by Hendrich II Fall Risk Model. Fibromyalgia Impact Questionnaire (FIQ), Nottingham Health Profile were used to determine functional level and quality of life and Beck Depression Inventory was applied to evaluate depression level. The assessments were performed at baseline and after six week at end of the exercise program.

Results: Exercise program was accomplished by 57 patients and there were no significant differences between group 1 ($n=28$, mean age=48.11±13.42) and group 2 ($n=29$, mean age=48.17±12.68) according to sociodemographic characteristics. In balance exercise group statistical significant improvements were observed in all parameters ($p<0.05$), however there was no improvement in flexibility exercise group ($p>0.05$) at sixth weeks. In the comparison of two groups, there were significant differences in balance group for KAT 4000 static balance ($p=0.017$) and FIQ measurements ($p=0.005$). Additionally negative correlation was shown between depression levels and BBS ($r=-0.434$, $p<0.01$), where as depression level was also correlated with fall risk ($r=0.357$, $p<0.01$).

Conclusions: A 6-week balance training program has found to have beneficial effect on static balance and functional level in patients with FMS, however it has no effect on dynamic and functional balance, and quality of life. It was observed that depression is correlated with balance deficit and fall risk.

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is associated with impaired balance and falls. *J Clin Rheumatol.* 2009 Feb;15(1):16-21.

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THU0325 LACK OF RELATION BETWEEN INFLAMMATION ON JOINT LEVEL AND FIBROMYALGIA SYMPTOMS IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Fibromyalgia (FM) exists in a substantial number of patients with rheumatoid arthritis (RA) (approx. 15%), who have higher disease activity as measured by DAS-28, than RA patients without concomitant FM. It is important to understand if there is an association between active inflammation on joint level and FM symptoms in RA patients

Objectives: In this study, we examined the relation between joint inflammation and FM symptoms in RA patients. We hypothesized that there is no correlation between the severity of inflammation on joint level and FM symptoms.

Methods: In a period of 8 months, RA patients (US-RA group) who were candidates to biological treatment underwent ultrasound (US) examination (Hitachi Preirus, 14 or 18 MHz linear transducer) before initiation of biological treatment. The patients underwent screening for fibromyalgia (FM) using The Modified 2010 American College of Rheumatology (ACR) Diagnostic Criteria. Two experienced ultrasonographers (SC, AC) blinded to the DAS-28 and FM results performed the UL examination, while experienced nurses, blinded on US and FM results performed the DAS28 calculation.

In a study made at the same period of time in our department we found that 13 RA patients in established biological treatment were diagnosed as having concomitant FM (RAF group). These patients were in a stable treatment during the examination time and there was calculate DAS-28 in the same way as above. The comparisons between US-RA and RAF groups were performed by unpaired t-test after confirming normal distribution of data.

Results: We included 13 patients in the US-RA group. They had at least two joints with high inflammation (Grey scale synovitis grade II and Colour Doppler grade II as minimum). They were screened for FM and only one of these patients fulfilled the Modified 2010 ACR diagnostic criteria. Three months later all patients were in DAS remission/low disease activity, except the patient with concomitant FM, who still had moderate high DAS because of many tender joints and high VAS-GH.

We also compared the US-RA group with RAF group and there was no significant difference in age, gender, disease duration & seropositivity. The rest of comparisons between the two groups are shown in Table 1.

Table 1

	US-RA (N=11)	RAF (N=13)	P-Value
WPI	3,5	8	0,0001
SS	5,5	7	0,007
DAS-28	4,6	4,0	ns
TJC	6,5	8	ns
SJC	5,5	0	0,003
VAS-GH	67,5	74,45	0,05
VAS-Fatigue	49	74,4	0,01
VAS-Pain	47,5	61	0,04
HAQ	0,93	1,75	0,012
CRP (mg/l)	11	2	0,05

WPI, widespread pain index; SS, symptom severity; TJC, tender joint count; SJC, swollen joint count.

Conclusions: We did not find evidence that RA patients with high inflammation on joint level have higher rates of FM. Biological naïve RA patients (US-RA group) with high level of joints inflammation as confirmed by US had less severe subjective symptoms (VAS & HAQ) compared to RAF patients in a stable biological treatment phase and without swollen joints.

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THU0326 RELATIONSHIP BETWEEN REGULAR EXERCISE, FUNCTIONAL CAPACITY AND QUALITY OF LIFE IN PATIENTS WITH FIBROMYALGIA

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Background: Fibromyalgia (FM) is a chronic musculoskeletal disorder characterized by generalized muscular pain accompanied by fatigue and tenderness at specific anatomical sites called tender points; additionally other associated symptoms include altered sleep, with cognitive and emotional disturbances as anxiety and depression, leading to disability and poor quality of life. Various exercise programs are accepted as treatment for FM, with complex actions on different muscular groups, leading to pain decrease, postural equilibrium and mobility improvement.

Objectives: Verify the relationship between functional capacity as well as a self

report of quality of life with the practice of regular exercise in patients with FM
Methods: A total of 320 patients diagnosed with FM were recruited between May of 2012 and December of 2013 from Rehabilitation outpatients clinics in Romania. The patients were divided in two groups. Group1 included patients who reported practice of regular exercise (n=170; 50,7±13,04 years), while group 2 included those who reported non-practice of regular exercise (n=150; 49±20 years). Functional capacity and quality of life was measured using the Health Assessment Questionnaire-HAQ and Short Form – SF-36

Results: Significant differences in the quality of life and functional capacity were observed when group 1 was compared with group 2. A lower score of functional capacity (HAQ) was found in group 2 when compared with the group 1 (p=0,0006). Higher values were obtained for the group 1 when compared with group 2 for the following domains of SF-36: physical functioning (p<0,001) and bodily pain (p<0,05). No significant differences were found for role physical, general health, vitality, social functioning, role emotion and mental health domains.

Conclusions: Regular exercise showed a positive impact in the functional capacity and quality of life in patients with FM.

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THU0327 EFFICACY OF VITAMIN D SUPPLEMENTATION IN THE TREATMENT OF FIBROMYALGIA: RANDOMIZED CONTROLLED TRIAL

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Background: Fibromyalgia (FM) is a condition characterized by chronic widespread musculoskeletal pain (MSK), fatigue and muscle tenderness. In addition, many patients have mood disturbances, report fatigue, disrupted sleep, balance disorders and decreased muscle strength. Reduced vitamin D levels are implicated in the pathogenesis of diffuse musculoskeletal pain in FM patients. A possible association between chronic widespread pain of FM and vitamin D deficiency has thus been suggested.

Objectives: To evaluate the efficacy of vitamin D supplementation in the treatment of FM.

Methods: Seventy-two consecutive FM patients diagnosed according to the American College of Rheumatology (ACR) 2010 criteria for FM were randomized into 2 groups, the first group (n=36) received oral cholecalciferol 2000 IU/day and the second group (n=36) received placebo for 6 months. Outcome measures included the Fibromyalgia Impact Questionnaire (FIQ), Brief Pain Inventory (BPI), Beck Depression Inventory (BDI), Visual analogue scale for pain (VAS 0-100mm) and Survey Short Form-36 (SF-36) assessment. Vitamin D levels were measured by Liaison immunoassay (normal 30–100 ng/ml). Serum levels between 10 and 30 ng/ml were classified as vitamin D insufficiency and levels <10 ng/ml as vitamin D deficiency. All measures were assessed at baseline and after 6 months. Safety and tolerability were also assessed.

Results: The mean 25(OH) D level at baseline was 19.9 ng/ml in patients compared to 28.5 ng/ml in controls. The overall prevalence of suboptimal and deficient 25(OH) D serum levels among patients with FM at baseline was 50/72 (69%) and 27/72 (38%), respectively. There was a statistically significant reduction in pain as shown by VAS scores in the intervention group compared to the placebo group (6.6±2.5 vs 2.9±2.7, p<0.001) at 6 months. Furthermore, there was a significant improvement in physical function (SF-36 and FIQ) scores. Lower 25(OH) D levels correlated significantly with higher FIQ scores, r =0.549; p<0.005). A statistically significant between-group difference was observed for depression as assessed by BDI. Optimization of vitamin D levels in FM had a positive effect on the pain perception.

Conclusions: Vitamin D may be an effective, cheap and useful addition to the therapeutic armamentarium for fibromyalgia. However, larger, long-term studies are required to confirm the results of the present study.

Disclosure of Interest: None declared

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THU0328 THE EFFICACY OF CLASSICAL INDIAN YOGA IN THE TREATMENT OF FIBROMYALGIA: A RANDOMIZED CONTROLLED TRIAL

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Background: Fibromyalgia (FM) is a complex musculoskeletal disorder treated with multidisciplinary therapies. It is manifested by widespread musculoskeletal pain, functional disability, sleep disturbances and poor quality of life. Classical Indian Yoga is an ancient life style healing technique which has an integrated mind-body approach to enhance both physical and mental health, thus having a positive impact in treatment of FM.

Objectives: To study the role of Classical Indian Yoga as an integrated mind-body healing approach in the comprehensive treatment of fibromyalgia.

Methods: This study incorporated a 6 months, single-blind, randomized trial of Classical Indian Yoga (50 patients) versus attention control group (stretching